



May 20, 2021

MEDRAD Interventional/Possis
Doug Atkins
Sr. Regulatory Affairs Associate
9055 Evergreen Blvd NW
Minneapolis, Minnesota 55433

Re: K101406

Trade/Device Name: AngioJet Solent Proxi Thrombectomy Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Doug Atkins:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 16, 2010. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'Connell -S Digitally signed by
Gregory W. O'Connell -S
Date: 2021.05.20
09:45:14 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

JUN 13 2010

MEDRAD Interventional / Possis
c/o Mr. Doug Atkins
Senior Regulatory Affairs Associate
9055 Evergreen Boulevard
Minneapolis, MN 55433-8003

Re: K101406
Angiojet Solent Proxi Thrombectomy Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE, KRA
Dated: May 18, 2010
Received: May 19, 2010

Dear Mr. Atkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

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found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Indications for Use

510(k) Number (if known): K101406

Device Name: AngioJet® Solent™ Proxi Thrombectomy Set

Indications for Use:

The AngioJet Solent Proxi Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from :

- upper and lower extremity peripheral arteries $\geq 3.0\text{mm}$ in diameter,
- upper extremity peripheral veins $\geq 3.0\text{mm}$ in diameter,
- ileofemoral and lower extremity veins $\geq 3.0\text{mm}$ in diameter,
- A-V access conduits $\geq 3.0\text{mm}$ in diameter and
- for use with the AngioJet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)


(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Cardiovascular Devices

510(k) Number K101406

K101406

JUN 13 2010

Section 5 – 510(k) Summary

Submitter: MEDRAD Interventional / Possis
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Minneapolis, MN 55433-8003 USA

Contact Person: Doug Atkins
Sr. Regulatory Affairs Associate
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Date Prepared: June 15, 2010

Trade Name: AngioJet[®] Solent[™] Proxi Thrombectomy Set

Classification: 870.5150 and 870.1210

Product Code: DXE and KRA

Predicate Device(s): The subject device is equivalent to the following devices:

- K091593 AngioJet Ultra DVX and Xpeedior Thrombectomy Sets

Device Description: AngioJet Solent Proxi Thrombectomy Set is a sterile, single use, disposable set that includes a Thrombectomy Catheter and Pump in one combined unit. The AngioJet Solent Proxi Thrombectomy Set is used with the AngioJet Ultra Console.

Intended Use: The AngioJet Solent Proxi Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:

- upper and lower extremity peripheral arteries $\geq 3.0\text{mm}$ in diameter,
- upper extremity peripheral veins $\geq 3.0\text{mm}$ in diameter,
- iliofemoral and lower extremity veins $\geq 3.0\text{mm}$ in diameter,
- A-V access conduits $\geq 3.0\text{mm}$ in diameter and
- for use with the AngioJet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

Comparison to predicate: Design changes were made to the predicate device which included: changes to the catheter shaft design, changes to the catheter manifold and tip to facilitate guide wire usage, and a change to the strain relief / manifold joint.

Performance Data: Bench and laboratory testing was performed to support a determination of substantial equivalence to the predicate device. Results from the testing provide assurance that the proposed device conforms to the requirements for its intended use. This included the following testing:

- Biocompatibility
 - Cytotoxicity (ISO 10993-5)
 - Intracutaneous Reactivity (ISO 10993-10)
 - Sensitization (ISO 10993-10)
 - Acute Systemic Toxicity (ISO 10993-11)
 - Material Mediated Pyrogen (ISO 10993-11)
 - Physiochemical (ISO 10993-18)
 - Hemocompatibility
 - ASTM Hemolysis (ISO 10993-4)
 - Partial Thromboplastin Time Assay (ASTM F2382-04)
 - C3a Complement Activation (ISO 10993-4)
 - SC5b-9 Complement Activation (ISO 10993-4)
 - Thromboresistance (ISO 10993-4)
- Catheter operational characteristics
- Leak testing
- Guide wire compatibility tests
- Particulate generation
- Tracking
- Extended use
- Kink resistance
- Corrosion
- Clot removal
- Hemolysis
- Catheter pass wall temperature
- Mechanical integrity (tensile strengths and compression / buckling)

Conclusion: MEDRAD Interventional / Possis considers the AngioJet Solent Proxi Thrombectomy Set to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.